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| 10/630,446 | 07/29/2003 | Navin Vaya | 1296-015 | 7784 |

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| EXAMINER | |
|---|---|
| MERCIER, MELISSA S | |

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| 1615 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/630,446 | VAYA ET AL. | |
| | Examiner | Art Unit | |
| | Melissa S. Mercier | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,2,4-34 and 36-74* is/are pending in the application.

4a) Of the above claim(s) *30,31,73 and 74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,2,4-29,32-34 and 36-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/12/07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Summary

Receipt of Applicants Remarks and Amended Claims filed on March 12, 2007 is acknowledged. Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### *Election/Restrictions*

Applicant's election with traverse of Group I in the reply filed on March 12, 2007 is acknowledged. The traversal is on the ground(s) that the examiner has not shown the claims are directed toward independent and distinct inventions. This is not found persuasive because inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to make tablets comprising the same active agents and does not require the use of a high dose and a low dose active ingredient.

The requirement is still deemed proper and is therefore made FINAL.

### *Information Disclosure Statement*

Receipt of the Information Disclosure Statement filed on March 12, 2007 is acknowledged.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4-29, 32-34, and 36-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The independent claims have been amended to delete the terminology "dual retard technique" and have added the terminology "micro matrix particles and coating on said micro matrix particles". After a review of the specification, written support for the definition cannot be found and applicant has not provided where the support for the amendment can be found.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-5, 8-11,14-29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glassman (US Patent 4,503,031) in view of Paradissis et al. (US Patent 5,445,829).

Glassman teaches, "a super-fast-starting, slow release medicinal tablet, wherein the tablet is comprised of two layers of compressed matrix that are fused together by means of a readily dissolvable adhesive substance, and in which one of the layers is a lightly compressed top layer containing a pure unadulterated, uncoated, active drug and which has one or more radial grooves in it's top surface to enhance rapid breakdown of the tablet; and the other layer has a strongly compressed portion comprised of a medically inert or inactive matrix having embedded throughout a multitude of pellets, each containing an active ingredient and having enteric coatings of various thicknesses so as to variably delay disintegration of the pellets" (abstract).

Glassman does not teach the pharmaceutical active as being highly soluble, the immediate release portion being a low dose, or the modified release being a high dose.

Paradissis teaches, "formulations composed of a mixture of 0 to 50% of an immediate release particle containing a core of drug, inert spherical substrate particles and binder, coated with talc and up to 100% of an extended release particle comprising the immediate release particle coated with a dissolution modifying

system containing plasticizers and a film forming agent, wherein the particle size of the extended release formulation is -10+60 mesh" (column 3, lines 21-33). The Examiner is interpreting the particle stated particle size for the extended release particles to include the coating; therefore the coating would be a micro matrix.

While the Paradissis patent does not specifically teach that the pharmaceutical actives must be highly soluble, it does teach, "a wide variety of medicaments which are orally administered as tablets maybe used, these include acetaminophen, which applicant provides as one example of a highly soluble active. "The drugs used in the formulations of Paradissis may be selected from a wide variety of pharmaceutical formulations with particular pharmaceutical compounds being analgesics, anti-inflammatories, antihistamines, antitussives, expectorants, decongestants, narcotics, antibiotics, bronchodilators, cardiovasculars, central nervous system (CNS) drugs, metal salts, minerals, vitamins and mixtures thereof" (column 3, lines 34-41). Further it would be obvious to one of ordinary skill in the art to substitute any active pharmaceutical into the teachings of Glassman and Paradissis.

Paradissis further teaches, "water-insoluble hydrophobic agents, such as diethyl phthalate, diethyl sebacate and castor oil are used to delay the release of water-soluble drugs, such as potassium chloride" (column 6, lines48-52) and "the film forming agents, which are also preferably employed in a spraying solution along with the plasticizer, may be selected from a wide variety of film forming materials. Preferable materials, however, may be selected from the group consisting of acrylic and

methacrylic acid copolymers and cellulose derivatives. Exemplary cellulose derivatives include ethylcellulose, methylcellulose, cellulose acetate, hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose and mixtures thereof" (column 7, lines 4-13).

Additionally, Paradissis teaches, "the extended release particles of the invention are then prepared by taking the immediate release particles and coating them with a dissolution modifying system which functions as a diffusion membrane around the coated core. The dissolution modifying system contains a plasticizer and a film forming agent which is applied by spraying the immediate release particles with about 2 to about 35% by weight of the dissolution modifying system coating. The dissolution modifying system is designed to encapsulate the particles and modify the drugs dissolution profile so that a sustained/extended drug release rate is obtained. In other words, the system is formulated to each drug profile to permit a release of the drug from the particles over a 12 to at least 24 hour period (column 6, lines 32-45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the percentages of coating on the micro matrix particles in order to provide the release of the modified release component that was desired.

Paradissis additionally teaches, "preferred plasticizers may be selected from the group consisting of diethyl phthalate, diethyl sebacate, triethyl citrate, crotonic acid, propylene glycol, butyl phthalate, dibutyl sebacate, castor oil and mixtures thereof" (column 6, lines 46-50).

Paradissis teaches, "formulations composed of a mixture of 0 to 50% of an immediate release particle containing a core of drug, inert spherical substrate particles and binder, coated with talc and up to 100% of an extended release particle comprising the immediate release particle" (column 3, lines 21-29).

While Paradissis does not teach the exact ratios of immediate release to modified release, it would be obvious to one of ordinary skill in this art to expand upon Paradissis to arrive at the instant claims.

Paradissis further teaches as a preferred embodiment "the formulation comprises from 0 to 50% of an immediate release particle containing a core of at least one drug, and up to 100% of an extended release particle which comprises the immediate release particle, additionally coated with a dissolution modifying system and optionally additional drug (column 3, lines 66-69, column 4, lines 1-4).

It would have been obvious to one of ordinary skill in the art that the time the invention was made to combine additional active ingredients to the tablet in order "to reduce the minimum daily number of doses from which the drug is uniformly released over a desired extended period of time" (column 1, lines 30-33).

Additionally, Paradissis teaches, "the rate of release of the pharmaceutical formulation may be described according to standardized dissolution testing procedures as found in the U.S. Pharmacopoeia XXII, where less than 50% of the drug is released within 1 hour of measurement and not less than 70% of the drug is released at the targeted dosing period, such as a 12 to at least 24-hour period (column 6, lines 39-45).

It is the Examiners position that Paradissis target dosing period includes the 6-hour dosing period of the instant application.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the coating thicknesses and particle sizes in order to make a dosage unit which will meet the release profile sought. One of ordinary skill in this art would be able to modify release profiles without undue experimentation.

Regarding Claim 28, Glassman teaches his "super-fast-acting, slow release tablet is capable of rapidly and predictably entering the Therapeutic Zone. The herein disclosed super-fast-acting, slow-release tablet (S/R) predictably enters into the Therapeutic Zone in the shortest possible time (less than one hour). That is 4-5 times faster than any known sustained release tablet, and it offers immediate and lasting therapeutic relief covering a period of 12 or more hours (column 4, lines 48-57). The Examiner is interpreting the 12 hours or more to be twice a day dosing.

Regarding Claim 29, Glassman teaches a study on asthmatic children who where given single dosages of uncoated tablets of Theophylline, which was not absorbed fast enough and therefore invented his tablet which combined uncoated and coated tablets. (column 4, lines 58-68). Therefore, it would be obvious to assume that Glassman intends his dosage forms to be used by human beings.

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being

recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of coating materials used in pharmaceutical compositions. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Glassman with the teachings of Paradissis in order to provide "the advantage of administering in a minimum of daily doses from which a drug is uniformly released over a desired, extended period of time. Various techniques have been developed for the purpose of including a pharmaceutical preparation comprising a drug-containing particle with a coating layer and a pharmaceutical preparation comprising a continuous matrix with a drug dispersed therein, such as embedded into a rigid lattice of resinous material" (Paradissis, column 1, lines 28-35).

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant argues the referenced art require the use of talc as a coating, however, it is noted that applicant has used the terminology "comprising which would allow for the inclusion of any number of additional components, which may or may not materially alter the dosage unit. Applicant further argues, neither Glassman nor Paradissis disclose the use of a combination dosage form having a low dose drug and a drug with a high solubility. As stated in the above rejection, it is the examiners position that it would be within the

knowledge of one of ordinary skill in the art at the time the invention was made to have selected any drug based on the desired effects and therapeutic benefits sought. Applicant further argues that it has been found by the present inventor that when the difference between the dosage strengths of two components of a dosage form is very high and particularly when the drugs are highly soluble, it is very difficult to provide a sustained release drug formulation. Nothing in the cited references addresses this problem. It is the examiners position that such a difference would be correctable and addressed through routine experimentation by one of ordinary skill in the art at the time the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glassman (US Patent 4,503,031) in view of Paradissis et al. (US Patent 5,445,829) and Webb et al. (US Patent 4,996 061).

The teachings of Glassman and Paradissis as they apply to Claim 1 are described above and applied in the same manner.

Glassman and Paradissis do not teach a tablet, in which the inner portion is covered by the outer portion from all sides except the top surface that remains uncovered.

Webb teaches, "a variation of the compression-coated tablet is the inlay tablet, also referred to as a dot, or bull's-eye tablet. Instead of an inner core zone being completely surrounded by an outer coat, one surface of the zone

corresponding to an inner core zone is exposed. These tablets have at least two discrete zones of granulation compressed together, i.e., an inlay zone and a base zone. The preparation of inlay tablets is similar to the preparation of compression-coated tablets except that a surface of coating is eliminated" (column 6, lines 3-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Glassman and Paradissis with the tablet of Webb in order to provide sustained-release of an active pharmaceutical with immediate release of another or the same active pharmaceutical.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments concerning the combination of Glassman and Paradissis have been discussed above. Applicant has not provided any additional arguments regarding the inclusion of Webb.

Claims 1, 6-7, and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glassman (US Patent 4,503,031) in view of Paradissis et al. (US Patent 5,445,829) and further in view of Lerner et al. (US Patent 5,840,332).

The teachings of Glassman and Paradissis as they apply to claim 1 are described above and applied in the same manner.

Lerner teaches, "a gastrointestinal delivery system is provided. The system comprises a drug in combination with a core material, the core being surrounded by a

water-insoluble or relatively water-insoluble coating material in which particulate water-insoluble material is embedded. When the delivery device enters the gastrointestinal tract, the particulate matter takes up liquid, thus forming channels interconnecting the drug-containing core with the outside of the delivery device. These channels allow the release of drug from the core into the gastrointestinal tract. By controlling parameters in the device, such as the core material, carrier material in the coating, and particulate matter, the location of release of the drug can be carefully controlled" (abstract).

Additionally, Lerner teaches, "the coating includes, but is not limited to, any combination of a water-insoluble polysaccharide, water-insoluble crosslinked polysaccharide, a water-insoluble polysaccharide metal salt, a water-insoluble crosslinked protein or peptide, a water-insoluble crosslinked hydrophilic polymer in a dried powder form as the particulate and any hydrophobic polymer coating known in the art as the water-insoluble carrier. Specific examples of the water-insoluble carrier include, but are not limited to, Eudragit E.TM., Eudragit NE.TM., Eudragit RL.TM., Eudragit RS.TM., ethylcellulose, shellac, zein, and waxes" (column 9, lines 38-65).

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited

teachings, instant claims are no more than the combination of conventional components of coating materials used in pharmaceutical compositions. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments concerning the combination of Glassman and Paradissis have been discussed above. Applicant has not provided any additional arguments regarding the inclusion of Lerner.

Claim 33, 36-37, 40-60, 62-65, 68-69, and 71-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glassman (US Patent 4,503,031) in view of Paradissis et al. (US Patent 5,445,829) and Timmins et al. (US Patent 6,475,521).

The teachings of Glassman and Paradissis as they apply are described above and applied in the same manner.

Glassman and Paradissis do not specifically teach the use of an antidiabetic ingredient as an active.

Timmins teaches "a biphasic controlled release delivery system for pharmaceuticals which have high water solubility, such as the antidiabetic metformin HCl salt, which includes a dosage form that has prolonged gastric residence so that a

dosing regimen of at least one gram metformin, preferably 1-3 grams, once daily, may be achieved while providing effective control of plasma glucose" (abstract).

Timmins further teaches, "metformin is an antihyperglycemic agent of the biguanide class used in the treatment of non-insulin dependent diabetes mellitus (NIDDM). It is usually marketed in the form of its hydrochloride salt as Glucophage" (column 1,lines 22-25).

While the Paradissis patent does not specifically teach that the pharmaceutical actives must be highly soluble, it does teach, "a wide variety of medicaments which are orally administered as tablets maybe used, these include acetaminophen, which applicant provides as one example of a highly soluble active. "The drugs used in the formulations of Paradissis may be selected from a wide variety of pharmaceutical formulations with particular pharmaceutical compounds being analgesics, anti-inflammatories, antihistamines, antitussives, expectorants, decongestants, narcotics, antibiotics, bronchodilators, cardiovasculars, central nervous system (CNS) drugs, metal salts, minerals, vitamins and mixtures thereof" (column 3, lines 34-41).

Timmins teaches, "the use of the metformin or salt thereof in combination with another anti-hyperglycemic agent produces antihyperglycemic results greater than that possible from each of these medicaments alone and greater than the combined additive anti-hyperglycemic effects produced by these medicaments. In addition, in accordance with the present invention a method is provided for lowering insulin resistance or treating hyperglycemia including type 2 diabetes (NIDDM) and/or type 1 diabetes (IDDM) wherein a therapeutically effective amount of the biphasic formulation of the

invention containing metformin or a salt thereof, optionally in combination with another antihyperglycemic agent and/or a hypolipidemic agent, is administered to a patient in need of treatment. The other antihyperglycemic agent may be an oral antihyperglycemic agent preferably a sulfonyl urea such as glyburide (also known as glibenclamide), glimepiride (disclosed in U.S. Pat. No. 4,379,785), glipizide, gliclazide or chlorpropamide, other known sulfonylureas or other antihyperglycemic agents which act on the ATP-dependent channel of the .beta.-cells, with glyburide being preferred" (column 12, lines 38-54).

Timmins's examples 1-3 provide dissolution profiles in which 33.1-38.1% of metformin was released at 1 hour, 57.5-79.7% was released at 4 hours, and 88.6-100% was released at 10 hours. (column 21-22). While a 12-hour time interval was not provided by, the profile parameters are met by 10 hours, therefore, they would inherently be met at 12 hours.

Timmons's Example 5 provides a table comparing Timmins's formulation of example 3 vs Glucophage. Timmins's Example 3 provides a Cmax (ng/mL) of 978, while Glucophage provides a Cmax of 1226. Glucophage is a commercially marketed product, which has been proven to be therapetucialy effective. Therefore, it would be obvious to one of ordinary skill in the art to make to prepare a dosage form, which would provide the equivalent parameters.

Timmins further teaches, "a controlled release dosage form, the formulator tries to reduce the rate of dissolution by, for example, embedding the drug in a polymeric matrix or surrounding it with a polymeric barrier membrane through which drug must

diffuse to be released for absorption. To reduce the rate of release of drug from the dosage form to an appropriate level consistent with the blood level profile desired for a drug possessing very high water solubility, very large amounts of polymer would be required for the matrix or barrier membrane" (column 2, lines 15-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the percentages of coating on the micro matrix particles in order to provide the release of the modified release component that was desired.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Glassman with the teachings of Paradissis in order to provide "the advantage of administering in a minimum of daily doses from which a drug is uniformly released over a desired, extended period of time.

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicants arguments concerning the combination of Glassman and Paradissis have been discussed above. Applicant has not provided any additional arguments regarding the inclusion of Timmons.

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glassman (US Patent 4,503,031) in view of Paradissis et al. (US Patent 5,445,829), Timmins et al. (US Patent 6,475,521), and Webb et al. (US Patent 4,996 061).

The teachings of Glassman, Paradissis and Timmins as they apply to Claim 33 are described above and applied in the same manner.

Glassman, Paradissis and Timmins do not teach a tablet, in which the inner portion is covered by the outer portion from all sides except the top surface that remains uncovered.

Webb teaches, "a variation of the compression-coated tablet is the inlay tablet, also referred to as a dot, or bull's-eye tablet. Instead of an inner core zone being completely surrounded by an outer coat, one surface of the zone corresponding to an inner core zone is exposed. These tablets have at least two discrete zones of granulation compressed together, i.e., an inlay zone and a base zone. The preparation of inlay tablets is similar to the preparation of compression-coated tablets except that a surface of coating is eliminated" (column 6, lines 3-15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Glassman, Paradissis and Timmins with the tablet of Webb in order to provide sustained-release of an active pharmaceutical with immediate release of another or the same active pharmaceutical

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicant's arguments concerning the combination of Glassman and Paradissis have been discussed above. Applicant has not provided any additional arguments regarding the inclusion of Timmons or Webb.

Claims 33, 36-39, and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Glassman (US Patent 4,503,031) in view of Paradissis et al. (US Patent 5,445,829), Timmins et al. (US Patent 6,475,521), and further in view of Lerner et al. (US Patent 5,840,332).

The teachings of Glassman and Paradissis as they apply to claim 33 are described above and applied in the same manner.

Lerner teaches, "a gastrointestinal delivery system is provided. The system comprises a drug in combination with a core material, the core being surrounded by a water-insoluble or relatively water-insoluble coating material in which particulate water-insoluble material is embedded. When the delivery device enters the gastrointestinal tract, the particulate matter takes up liquid, thus forming channels interconnecting the drug-containing core with the outside of the delivery device. These channels allow the release of drug from the core into the gastrointestinal tract. By controlling parameters in the device, such as the core material, carrier material in the coating, and particulate matter, the location of release of the drug can be carefully controlled" (abstract).

Additionally, Lerner teaches, "the coating includes, but is not limited to, any combination of a water-insoluble polysaccharide, water-insoluble crosslinked polysaccharide, a water-insoluble polysaccharide metal salt, a water-insoluble crosslinked protein or peptide, a water-insoluble crosslinked hydrophilic polymer in a dried powder form as the particulate and any

hydrophobic polymer coating known in the art as the water-insoluble carrier. Specific examples of the water-insoluble carrier include, but are not limited to, Eudragit E.TM., Eudragit NE.TM., Eudragit RL.TM., Eudragit RS.TM., ethylcellulose, shellac, zein, and waxes" (column 9, lines 38-65).

It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of coating materials used in pharmaceutical compositions. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive. Applicants arguments concerning the combination of Glassman and Paradissis have been discussed above. Applicant has not provided any additional arguments regarding the inclusion of Timmons or Lerner.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

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Primary Examiner
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